FEB 21 2001 K003792

stryker®
ENDOSCOPY

SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Classification Name:	Laparoscopic CO_2 Insufflator
Common and Usual Name:	Disposable Insufflator Tube Set with Gas Warming
Proprietary Name:	Stryker Heated Insufflator Tube Set

Predicate Device

Disposable heated tube set described in 510(k) #K955791, Surgiflator 20 PIM, and 510(k) #K973432, Surgiflator 30.

Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with requirements of SMDA 1990.

The Stryker Heated Insufflator Tube Set consists of flexible tubing with conductor wire bonded along the outside that completes a circuit from the insufflator consoles heating board to the heating element and heating control components inside the distal end of the tube set. The tube set will be packaged sterile and labeled for single use only. When the heating element is plugged into a Stryker Insufflator console, the tube set will heat the insufflation gas as it flows through the tube set to a preset, non-variable, 37°C.

This device is intended for use by general surgeons in laparoscopic procedures to provide a path for the insufflation gas from the insufflation device to the patient. When used with an insufflator with heating capabilities, this device will also warm the gas.

The technological characteristics of the Stryker Heated Insufflator Tube Set are equivalent to that of the predicate device. In addition, laboratory temperature and flow testing has shown the performance of the Stryker tube set to be equal to or exceed that of the predicate device.

The tube set components contacting the patient are constructed of materials which are tested for biocompatibility per ISO-10993 and General Program Memorandum #G95-1. Tube set sterilization will be per EN 550 (Ethylene-oxide) or EN 552 (Irradiation) with sterility validated to a minimum sterility assurance level of 10^{-6}.

The Stryker Heated Insufflator Tube Set is equivalent in safety and efficacy to the W.O.M. disposable insufflator tube set with gas warming currently being sold by Stryker.

The Stryker Heated Insufflator Tube Set does not raise new issues when compared to the currently marketed predicate devices. Therefore, it is considered substantially equivalent to those devices.

Contact:

Michael Baycura (Sr. Product Engineer)
Stryker Endoscopy
2590 Walsh Ave.
Santa Clara, CA 95051
(408) 567-9100

Date: January 7, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2001

Mr. Michael Baycura
Senior Product Engineer
Stryker® Endoscopy
2590 Walsh Avenue
SANTA CLARA CA 95051

Re: K003792
Stryker® Heated Insufflator Tube Set
Dated: November 17, 2000
Received: December 8, 2000
Regulatory Class: II
21 CFR §884.1730/Procode: 85 HIF

Dear Mr. Baycura:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

January 7, 2000

510(k) Number if known: K003792

INDICATION FOR USE:

This device is intended for use by general surgeons in laparoscopic procedures to provide a path for the insufflation gas from the insufflation device to the patient. When used with an insufflator with heating capabilities, this device will also warm the gas.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

(Per 21 CFR 801.109)

David A. Bryan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003792